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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,518	11/30/2000	Martin Friede	B45139	8200

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[REDACTED] EXAMINER

CEPERLEY, MARY

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 01/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/647,518	FRIEDE ET AL
Examiner	Art Unit	
Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24,30,32-35 and 37 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-24,30,32-35 and 37 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u>	6) <input type="checkbox"/> Other: _____

1. The specification must be amended to include a section entitled "Brief Description of the Drawings".
2. There are two claims numbered "claim 20". Correction is required. For the purpose of this Office action, the second "claim 20" will be referred to as "claim 20(a)".
3. In claim 21, the spelling of "polylactide" should be corrected. In claim 35, line two, "and" should be -- an--.
4. Claims 19, 20, and 20(a) are improper multiply dependent claims which depend from other multiply dependent claims.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

8. Claims 1-3, 7, 8, 10, 13-20, 20(a), 21, and 32-35 are rejected under 35 USC 112, first paragraph, as being based on a specification which does not contain an adequate enabling written description of the invention.

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a) For claim 1, there is no enabling written description in the specification of a composition wherein the surfactant is in the form of a "micelle".

b) For claim 2, there is no enabling written description in the specification to support the negative limitation "does not comprise an acrylic acid polymer".

c) For claim 3, there is no enabling written description in the specification to support the negative limitation "does not comprise an oil-in-water or water-in-oil emulsion".

d) For claim 18, there is no enabling written description in the specification of the immunostimulants "3D-MPL" and "QS21".

e) For claim 30, there is no enabling written description in the specification of the "spray device" of claim 30.

f) There is an inadequate enabling written description in the specification to support a method of use of the claimed composition for the treatment of all types of "pathogenic infections" and all types of "cancer". The term "pathogenic infections" and "cancer" are inclusive of a wide variety of diseases of different etiologies. The prior art does not establish that all of the encompassed diseases are effectively treated/prevented with a corresponding antigenic vaccine.

9. Claims 15 and 30 are rejected under 35 USC 112, second paragraph, as being indefinite for the following reasons.

a) The claim 15 term "selected from the group comprising" is inconsistent with the accepted Markush group terminology "selected from the group **consisting of**".

b) Regarding claim 30, the phrase "more particularly" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The instant claims may be characterized as follows. The broadest claims (e.g. claim 1) are drawn to "compositions" which require only one component i.e. an "adjuvant" comprising a compound of formula (I), in water. These claims are readable on (i.e. are anticipated by) any/all prior art which describes an aqueous solution of a compound of the formula I (e.g. known compounds Triton X-100, Brij 30 or Brij 35). {Note that claim 37 requires only "a pharmaceutically acceptable excipient", "an antigen" and a specific "adjuvant" and does not require that the "adjuvant" be present in any particular form.} The claim preamble limitation "adjuvant" does not lend any patentable weight to a "composition" *per se*. Other claims require both the compound of formula (I) in combination with an antigen. However, it is noted that claims which require only the presence of an "adjuvant" also contain open-ended "comprises" terminology which does not exclude the presence of an additional "antigen" component. Therefore,

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these "adjuvant" claims are properly rejected over the same art which may be pertinent to the "vaccine" compositions. Note that **water** constitutes "a pharmaceutically acceptable excipient".

13. Claims 1-24, 30, 32-35 and 37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Brown (*Aerosol Science and Technology*, 24(1), 45-56 (1996)), Ullman et al (*Archiv. der Parmazie*, 305 (797-803 (1972))), Teerlink et al (*Vaccine*, 5, 307-314 (1987)), Berezin et al (*Vaccine*, 6, 450-456 ((1988))), Longenecker et al (*J. Pharm. Sci.*, 75(5), 351-355 (1987)), Fontan et al (*Internat'l. J. Pharmaceutics*, 73, 17-21 (1991)), Rinella et al (*J. Colloid and Interface Sci.*, 197, 48-56 (1998)), Morein (U.S. 5,254,339), Modi (U.S. 6,221,378), Moste-Deshairs et al (U.S. 5,741,493), De Vries et al (U.S. 4,900,549), Modi et al (U.S. 5,653,987), Glass et al (U.S. 3,919,411), PROTEUS (WO 95/09651), MICRO VESICULAR WO 88/06882), or Fontan et al (Chemical Abstract 115: 119977).

Each of the references describes an aqueous solution or micelle of a compound described by formula (I) of instant claim 1 which anticipates the composition of instant claim 1. The references further describe combinations of this "adjuvant" with an additional moiety which may be characterized as an "antigen". These combinations anticipate the "vaccine" compositions of the instant claims. Note that instant claim 37 is even broader than claim 1 and does not require that the antigen be present in the composition in either an "aqueous solution" or a "micelle" form.

See: Brown: Abstract, bovine gammaglobulin; page 46, *Aerosols*: laureth-9 (polyoxyethylene-9-lauryl ether) in PBS; Ullman et al: English abstract, nicotinic acid esters; Tables 1 and 2; Teerlink et al: Abstract, *Neisseria gonorrhoeae*; Triton X-100; Berezin et al: viral vaccines, Triton X-100; *Purification of glycoproteins*; Longenecker et al: insulin, Table 1: Polyoxyethylene 9 lauryl ether; Fontan et al: Summary: Brij 35 and Simulsol M, carbamazepine; Rinella et al: Abstract, model vaccines, Triton X-100; Morein: Abstract, antigenic proteins; col. 5, lines 38-52; Modi: abstract, proteinic pharmaceutical agent; col. 4, lines 12-32: octylphenoxypolyethoxyethanol; Moste-Deshairs et al: abstract, influenza virus; col. 2, lines 23-30, Triton X-100; De Vries et al: abstract, amphipathic antigenic protein; col. 3, lines 3-8; Modi

et al: abstract, polyoxyethylene X-lauryl ether; col. 3, line 57 – col. 4, line 3; Glass et al: col. 6, lines 40-42: Brij 30 and Brij 35; PROTEUS ('651): page 6, lines 17-30; MICRO VESICULAR: abstract; PAGE 9, LINES 16-31; Fontan et al: polyoxyethylene 50-stearate and polyoxyethylene 23-lauryl ether; carbamazepine.

The open-ended "comprises" terminology of the instant claims does not exclude the presence of additional components in the composition and the "adjuvant" limitation does not lend patentable weight to the "adjuvant" composition *per se*. See the discussion of paragraph 12. above.

The features of the independent and dependent claims are either specifically described by the references (e.g. for the influenza virus of instant claim 23, see Moste-Deshairs et al; for a micelle formulation, see Modi; for use of a spray device, see Modi, col. 11, lines 43-49), inherently present in the compositions (e.g. haemolytic activity), or constitute obvious variations in parameters which are routinely modified in the art (e.g. concentration of active ingredient (claim 16); additional conventional vaccine compositions components (claim 18); conventional use and preparation of a vaccine (claims 32 and 35)) and which have not been described as critical to the practice of the invention.

14. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Singh et al (JAOCS, 61(3), 596-599 (1984)).

Singh et al describe aqueous compositions containing ether compounds which are encompassed by formula (I) of instant claim 1. These compositions anticipate the compositions of instant claim 1. See the discussion of paragraph 12. above. See Singh et al: TABLE I: Sterox-NJ, Surfactant-WK and Triton X-114. The features of the dependent claims are either specifically described by the reference (e.g. aqueous solution), are inherently present in the compositions (e.g. haemolytic activity) or constitute obvious variations in parameters which are routinely modified in the art (e.g. specific form of the surfactant i.e. micelle, vesicle, etc.) and which have not been described as critical to the practice of the invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

January 22, 2002

Mary E. Ceperley
Mary E. Ceperley
Primary Examiner
Art Unit 1641